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SEP 03 2002

In re application of:

Yongwei CAO *et al.*

Appln. No.: 09/404,520

Filed: September 23, 1999

For: *Emericella nidulans* Genome Sequence
and Uses Thereof

Art Unit: 1656

TECH CENTER 1600/2900

Examiner: T.E. STRZELECKA

Atty. Docket: 16517.081

Petition under 37 C.F.R. §1.181Commissioner for Patents
Washington, DC 20231

Sir:

Responsive to the Decision on Petition mailed July 10, 2002, Applicants hereby petition the Commissioner to reconsider the Decision on Petition denying the request to withdraw the Restriction Requirement in the above-identified application. Applicants likewise request the Commissioner to withdraw the restriction requirement and re-open prosecution in the above-identified application. This petition is timely-filed within two months of mailing of the Decision on Petition.

A. Statement of Facts

1. Application Serial No. 09/404,520 was filed September 23, 1999, and disclosed about 12,000 genes or partial genes of the filamentous fungus *Emericella nidulans*, also commonly known as *Aspergillus nidulans*. The DNA fragments from genomic sequencing were assembled into large contiguous sequences, resulting in 16,206 separate DNA sequences, disclosed as SEQ ID NOS: 1 – 16206. The sequences were analyzed by homology-based and predictive-based methods to identify 11,958 predicted genes disclosed in the sequence list as SEQ ID NO: 16207 through SEQ ID NO: 28165. *See* Ser. No. 09/404,520 at 4, lines 10 to 23.

2. The application was originally filed with 46 claims. In the Office Action mailed February 12, 2001, the Examiner required restriction of the claims to one of eleven groups. *See* Office

Action mailed February 12, 2001 at 2-4. In the same Office Action, the Examiner required Applicants to elect a single nucleic acid sequence for examination, citing MPEP §803.04. *Id.* at 9.

3. In response to the restriction requirement imposed by the Examiner, Applicants provisionally elected, with traverse, the subject matter of Group XI comprising original claims 29 and 30 and submitted a preliminary amendment which included characterizing the claimed subject matter by a Markush group including 11,698 genes and partial genes having nucleotide sequences selected from the group consisting of SEQ ID NO 16207 through 27905. *See* Response to Restriction Requirement and Preliminary Amendment at 2. Because these genes were identified by homology-based methods, they all have an assigned function.

Although Applicants expressed their belief that the claimed invention should be examined without the sequence restriction, applicants provisionally elected a 100 nucleotide sequence set (SEQ ID NOS: 16207 through 16306) and the single sequence (SEQ ID NO 16207) for examination. *See* Response to Restriction Requirement and Preliminary Amendment at 2. The then-amended claim 29 and newly added claims 57 and 58 illustrate the key aspects of the invention as follows:

29. (Amended) Computer readable medium having recorded thereon at least 100 of the nucleotide sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.

57. (New) A computer based system comprising computer readable medium of claim 29, input means for receiving a target sequence, means for identifying fragments of sequence recorded in said computer readable medium which are homologous to a target sequence, and an output means for outputting identified homologous sequences.

58. (New) A method of identifying nucleotide sequence comprising comparing target sequence to a sequence stored in computer readable medium of claim 29.

Id. at 2-3. Finally, Applicants requested an interview with the Examiner based on Applicants' belief that the restriction to a single nucleotide sequence prevented the examination of the Applicants' claimed invention. *Id.* at 2.

4. In the Office Action mailed May 23, 2001, the Examiner indicated that claims 57 and 58 contained allowable subject matter, but repeated the election of a single nucleotide sequence requirement citing MPEP §803.04. *See* Office Action mailed May 23, 2001 at 2.

5. In the Amendment of October 23, 2001, Applicants canceled all pending claims except claims 57 and 58. *See* Amendment dated October 23, 2001 at 1. Applicants then rewrote claims 57 and 58 in independent form¹. *Id.* at 2.

6. On October 26, 2001, Examiner Strzelecka spoke with Applicants' representative and stated that the application could be passed to issue if the claims were amended to refer only to the single sequence searched. Applicants refused to authorize an Examiner's amendment limiting the claims to a single sequence because a computer system and search method limited to a single sequence would be essentially valueless and merely a sham easily avoided by others who could use the full value of applicants' invention with impunity.

7. On December 28, 2001, a final Office Action was mailed leaving Applicants with a Hobson's choice of limiting the otherwise allowable claims to a single sequence or abandoning the application. *See* Final Office Action at 2.

8. On March 27, 2002, Applicants' representative filed a Petition under 37 C.F.R. § 1.144 requesting review of the restriction requirement essentially arguing that the restriction requirement is contrary to Patent Office policy, as provided in the MPEP, and that the restriction requirement effectively denies Applicants their statutory right to their invention which, in this

¹ The claims currently pending in the application read as follows:

57. A computer based system comprising computer readable medium having recorded therein at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, input means for receiving a target sequence, means for identifying fragments of sequence recorded in said computer readable medium which are homologous to a target sequence, and an output means for outputting identified homologous sequences.

58. A method of identifying nucleotide sequence comprising comparing target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.

case, is properly set forth in a claim comprising a Markush group of a plurality of sequences.
See Petition at 4.

9. On July 10, 2002, the Technology Center Director issued a Decision on Petition denying Applicants' Petition. In sum, the Decision finds that the present claims are directed to a computer system wherein the sequence data is considered non-functional descriptive material rather than a physical entity such as a composition or molecule. The Decision then goes on to cite to the examination guidelines for computer related inventions. *See* Decision at page 6.

B. Summary of Arguments

Applicants respectfully petition the Commissioner to review the Decision on Petition denying the request to withdraw the restriction and election requirement in the above-captioned matter. Applicants further request that the restriction and election requirement be withdrawn, and that prosecution be re-opened. The required restriction and election of a single sequence are overly restrictive and effectively deny Applicants their statutory right to their invention which, in this case, is properly set forth in a claim comprising a Markush group of a plurality of sequences.

The requirement that Applicants elect only a single nucleotide sequence for issuance in the present application effectively nullifies the advantages and value of the disclosed invention. In the instant case, the single sequence policy effectively forces Applicants to file 11,698 applications to obtain exclusive rights to their invention. If, for the sake of argument, the nominal out of pocket cost for a patent from cradle to grave including filing, issue and maintenance fees is \$8,000, Applicants are faced with the unconscionable economic burden of about \$100 million (about 1% of the annual USPTO budget). Moreover, even this expenditure would not allow Applicants to claim what they regard as their invention. As such, Applicants

respectfully submit that the Commissioner has effectively denied Applicants their right to claim their invention.

C. Applicants Have Been Effectively Denied Their Statutory Rights in the Disclosed Invention

Applicants' claims are directed to a computer based system comprising a computer readable medium having recorded thereon at least 100 nucleotide sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof and methods for identifying a particular sequence within this group. By requiring Applicants to select only a single sequence to issue in the claims, the actions of the Examiner effectively redefined Applicants' invention as an isolated composition rather than as a computer related invention.

More particularly, Applicants are not claiming nucleotide sequences in isolation. The claims are directed to a computer based system and a method which allows one to search the genome of the filamentous fungus *Emericella nidulans* for a target sequence, a fragment of that sequence, or a complement. Not only does implementing an election of a single sequence in the present application effectively destroy the value of the invention as a tool for locating specific sequences in the genome of this fungus, but it is also an attempt to rewrite the claims to another invention. In other words, the claims in the present application have been effectively rejected under 35 U.S.C. §121 because of the Examiner's belief that they are directed to "independent and distinct" inventions. Final Office Action at page 2. However, imposing this type of rejection for a Markush claim is improper as a matter of law. *In re Weber*, 580 F.2d 455, 459, 198 U.S.P.Q. 328, 332 (C.C.P.A. 1978) (holding "that a rejection [of a Markush claim] under §121 violates the basic right of the applicant to claim his invention as he chooses"). As stated above, the Applicants' invention is not directed to a single nucleotide or even a group of nucleotides, but rather to tools and methods for identifying a particular sequence or fragment thereof in the genome of *Emericella nidulans*. Therefore, the restriction requirement in the present application is improper.

D. Conclusion

In view of the arguments above, Applicants specifically petition the Commissioner to return this application to the Examiner with instructions to re-open prosecution and examine 100 of the selected sequences recited in claims 57 and 58.

Arnold & Porter check number 9206392 submitted herewith, includes payment of the fee of \$130.00 for filing a Petition to the Commissioner (37 C.F.R. § 1.17(h)). In the event that extensions of time under 37 C.F.R. § 1.136, other than those otherwise provided for in the papers accompanying this Notice are required to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, and/or credit any overpayment, to our Deposit Account No. 50-1824, referencing docket number 16517.081.

Respectfully submitted,



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